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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,718	10/01/2004	Hyung Joo Kim	61282.00018	4384
30256	7590	01/03/2006	EXAMINER	
SQUIRE, SANDERS & DEMPSEY L.L.P			MARTIN, PAUL C	
600 HANSEN WAY			ART UNIT	
PALO ALTO, CA 94304-1043			PAPER NUMBER	

1655

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,718	Applicant(s) KIM ET AL.	
	Examiner Paul C. Martin	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/24/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-5 are pending in this application and were examined on their merits.

Claim Objections

Claim 4 is objected to because of the following informalities: Line 4d should have the letter "s" added to the words "control" and "determine". The Abbreviation "PC" should be defined whenever it first appears. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: The letter "a" should be inserted in between the words "and" and "sample" in the third line of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1655

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims encompass a method for detecting toxic materials in water using an electrochemically active microorganism.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. MPEP § 2163.

Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic.

In re Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe the subgenus. *In re Gostelli*, F.2d at 1012, USPQ2d at 1618.

As stated *supra*, the MPEP states that the written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable, that Claim 1 is a broad generic, with respect to all possible water borne toxic materials and all possible electrochemically active microorganisms. The possible viable species of microorganisms that have the ability to produce electrochemical signals is vast, no distinct species is disclosed in the specification, and examples reflecting the variety of possible species in the genus are not provided. The genus of water-borne toxic materials is likewise largely undefined in the specification, and the number of organic and in-organic toxins is substantial. The specification only provides one working example of detected toxin, well short of the court defined constitution stated above.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the electrochemically active microorganisms as disclosed by Nakamura *et al.* (US 5,160,604) does not reasonably provide enablement for all possible species of electrochemically active microorganism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404).

Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

The specification at hand makes no specific instruction as to what microorganism (bacteria, fungus, algae, etc.) the invention is to utilize. Further, no working examples are provided in the instant specification so as to enable any ordinary artisan to make and use the claimed invention without undue experimentation to discover workable electrochemically active microorganisms.

For instance, Wilkins (1978) measured detectable electrochemical activity successfully from 14 representative species of gram-positive and gram-negative bacteria.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the **entire scope** of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitations "The method" and "the electrochemically active microorganism" in the first sentence. There is insufficient antecedent basis for these limitations in the claim. Correction to "A method..." and "...an electrochemically..." is recommended.

Claim 2 recites the limitations "The method" and "the microbial fuel cell" in the first sentence of the claim and line 2a respectively. There is insufficient antecedent basis for these limitations in the claims. Correction to "A method..." and "...a microbial fuel cell" is recommended.

Claim 2 recites the limitation "...the above microbial fuel cell" in line 2b. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitations "The device..." and "...the above microbial fuel cell" in the first line and last line of the claim respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "The device..." in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "The device..." in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 and 5 contain reference numerals throughout the body of the claims which seem to refer to some unspecified figure, it is unclear to what, if anything the numerals correspond to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura *et al.* (US 5,160,604).

Art Unit: 1655

Nakamura *et al.* teaches a method for detecting toxic materials in water using electrochemically active microorganisms, comprising the steps of:

Determining the stable sensor output as a reference point (Column 4, Lines 12-22), introducing a water sample into the microorganism sensor (Column 11, Lines 20-26), and determining the degree of electrochemical signal changes (Column 11, Lines 27-42).

Nakamura *et al.* teaches a device for detecting toxic materials in water comprising:

An inlet pump (Fig. 2, #32), a first pretreatment tank for pre-treating the water sample (Column 6, Lines 64-68), a microorganism sensor which detects changes in current due to the entry of toxic materials (Fig. 4), and a computer and control circuit which controls the value of the signals and automatically determines the toxicity (Column 8, Lines 58-68 and Column 9, Lines 1-15)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (US 5,160,604) in view of Park *et al.* (US 2001/0026936 A1) and Shedd *et al.* (US 6,058,763).

The teachings of Nakamura *et al.* were discussed *supra*.

Nakamura *et al.* does not teach the step of screening out unwanted suspended material and debris from the water sample prior to introducing the sample to the microorganism sensor.

Nakamura *et al.* does not teach the use of a solenoid valve which changes the flow of the sample when entry of toxic materials is sensed, or a sample-gathering vessel which intakes and stores the sample when toxic materials are detected.

Park *et al.* teaches the use of a filter that prevents the entering of non-liquid substances in a sample prior to introducing the sample to wells containing luminescent microorganisms. (Page 2, Column 1, Lines 48-49).

Shedd *et al.* teaches a device for detecting toxic materials in water comprising a solenoid valve (Column 14, Line 1) which changes the flow of the sample when toxic materials are detected (Column 14, Lines 16-25), and a sample-gathering tank which intakes and stores the sample upon detection of toxic substances (Column 11, Lines 12-15)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Nakamura *et al.* with the use of a pre-filter to screen out suspended matter and prevent clogging downsystem. This step would increase efficiency of the system and prevent costly downtime and maintenance due to contamination and cleaning. The ordinary artisan would also have recognized that diversion and retention of a contaminated sample would be prudent until further analysis and/or corrective action could be taken. The ordinary artisan would have been motivated to make these modifications due to the increased efficiency, cost-effectiveness provided and good standard operating practices regarding water-borne toxins. The ordinary artisan would have had a reasonable expectation of success based on the previous use of those modifications in similar water-borne toxin detecting systems.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

12/15/05

PATRICIA LEITH
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Patricia Leith', is written over a rectangular stamp. The signature is fluid and cursive, with a long horizontal stroke extending to the right.